DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GENORAY Co., Ltd.
% Ms Kaitlynn Min
Business Developer Manager
GENORAY America, Inc.
3002 Dow Avenue, Suite 420
TUSTIN CA 92780

December 10, 2015

Re: K150354
Trade/Device Name: PAPAYA 3D Plus
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS, MUH
Dated: November 17, 2015
Received: November 18, 2015

Dear Ms. Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150354

Device Name
PAPAYA 3D Plus

Indications for Use *(Describe)*

PAPAYA 3D Plus is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in:

(i) producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and
(ii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with the cephalometric arm;
(iii) producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition(teeth), jaws ,oral structures and some cranial bones if equipped with CBCT option.

The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing twodimensional views of this volume and displaying both two dimensional images and three-dimensional renderings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Exhibit 5 510(k) Summary

Date of Summary Preparation: Feb 01, 2015

1. Submitter and US Official Correspondent

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2. Establishment Registration Number

3005843418

3. Device Information

Trade/Device Name: PAPAYA 3D Plus

Regulation Name: Computed tomography X-ray System

Classification Name/Product Code: X-ray, Tomography, Computed/OAS
System, X-ray, Extraoral Source, Digital / MUH

Device Class: Class II per regulation 21 CFR 892.1750

4. Predicate Device (Equivalent Legally Marketed Device)

Hyperion X9 (K123381, Cefla S.C.)
PAPAYA Plus (K141700 Genoray Co., Ltd)

5. Description of the Device

PAPAYA 3D Plus is a diagnostic imaging system which consists of multiple image acquisition modes; panorama, cephalometric, and computed tomography. PAPAYA 3D Plus designed for dental radiography of the oral and craniofacial anatomy such as teeth, jaws and oral structures.

PAPAYA 3D Plus is equipped with extra-oral flat panel x-ray detectors which is based on CMOS digital X-ray detector and has CT, panoramic and cephalometric radiography with an extra-oral x-ray tube. CMOS Flat panel detectors are used to capture scanned image for obtaining diagnostic information for craniofacial surgery or other treatments. And it also provides 3D diagnostic images of the anatomic structures by acquiring 360°rotational image sequences of oral and craniofacial area.

6. Indications for use (intended use)

PAPAYA 3D Plus is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in:

(i) producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and
(ii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with the cephalometric arm;
(iii) producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition(teeth), jaws ,oral structures and some cranial bones if equipped with CBCT option.

The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings.

7. Substantial equivalence chart

Name	Proposed device PAPAYA 3D Plus	Hyperion X9	PAPAYA Plus
Manufacturer	GENORAY Co., Ltd.	CEFLA S.C.	GENORAY Co., Ltd.
510(k) No.	-	K123381	K141700
Indications for use	PAPAYA 3D Plus is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in: (i) producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and (ii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with the cephalometric arm; (iii) producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition(teeth), jaws ,oral structures and some cranial bones if equipped with CBCT option. The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings.	Hyperion X9 is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in: (i) producing panoramic X-ray images of the maxillofacial area, for diagnostic examination of dentition (teeth), jaws and oral structures; and (ii) producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination, when equipped with tele-radiographic arm (CEPH); (iii) producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition (teeth), jaws ,oral structures and some cranial bones if equipped with CBCT option. The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings.	P AP A Y A Plus is a digital extraoral source X-ray system intended to produce panoramic and cephalometric(option) images of the oral and craniofacial anatomy for a precise treatment planning in adult and pediatric care. The system is used for dental & skull radiographic examination and diagnosis ofteeth,jaw, oral structure, and skull by exposing an X-ray image receptor to ionizing radiation, with a digital imaging capability for taking both panoramic and cephalometric images. And this system can be equipped CUST(Tomographic) option, which is capable of taking cross-sectional radiographic images. These images provide dimensional information for dental implant planning and information about location of impacted teeth

Name	Proposed device PAPAYA 3D Plus	Hyperion X9	PAPAYA Plus
Performance Specification	Panoramic Cephalometric Computed tomography	Panoramic Cephalometric Computed tomography	Panoramic Cephalometric Tomography
3D Technology	Cone beam Computed tomography	Cone beam Computed tomography	Volumetric tomography
CT FOV (D×H)	14×14, 14×8, 8×8, 7×7, 4×4cm	11×8, 11×5, 8×8, 8×5, 5×5cm	4.8×10
Input Voltage	100-120V~	115 - 240 V~	100-120V~
Tube Voltage	60-90 kV	60-90 kV	60-90 kV
Tube Current	4-12 mA	1-10 mA	4-12 mA
Focal Spot Size	0.5 mm	0.5 mm	0.5 mm
Exposure Time	PANORAMA: max 17sec CEPHALO: max 12sec CT : max15sec	160ms – 18 sec	Standard Panorama: 12 sec Cephalo(Normal): 8 sec
Image Receptor	Panoramic: CMOS FPD Cephalometic: CMOS FPD CBCT: CMOS FPD	Panoramic: CCD Cephalometic: CCD CBCT: Amorphous Silicon FPD	Panoramic: CMOS FPD Cephalometic: CMOS FPD

The proposed PAPAYA 3D Plus was developed from the PAPAYA Plus(k141700) by adding Computed tomography function. Accordingly, the characteristics of the PAPAYA 3D Plus are identical or similar to those of the PAPAYA Plus(k141700) regarding X-ray generation device characteristics including tube voltage, tube current, focal spot size and X-ray image capturing device including type of detector.

The differences of the PAPAYA 3D Plus from the PAPAYA Plus(k141700) are the addition of detector options and Computed tomography function.

New SSXI detectors are Extor-P for Panorammic mode, Extor-C for Cephalo mode, and DualRay-S for CBCT mode. They are for the newly upgraded PAPAYA Plus(k141700). Remaining detectors are the same, the non-clinical & clinical considerations are also equivalent, and the report regarding non-clinical & clinical consideration for the added new detectors are provided separately.

The Computed tomography function of the PAPAYA 3D Plus is similar to Hyperion X9(k123381). The system accomplishes tomographic exam by acquiring a 360-degree rotational X-ray sequence of images and reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume and displaying both two dimensional images and three-dimensional renderings. It is known as CBCT.
The PAPAYA 3D Plus has the similar characteristics regarding intended use, X-ray generation device characteristics including tube voltage, tube current, and focal spot size as Hyperion X9(k123381). The PAPAYA 3D Plus has the same indication for use as the Hyperion X9(k123381).

8. Safety, EMC and Performance data comparison to Predicate

PAPAYA 3D Plus complies with industry standards such as IEC 60601-1 Series and 21 CFR 1020.30 and 21 CFR 1020.31 and 21 CFR 1020.33 to minimize electrical, mechanical and radiation hazards.

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-3, and IEC 60601-2-63 were performed.
- EMC testing was conducted in accordance with standard IEC 60601-1-2.
- Acceptance test according to standard IEC 61223-3-4 and IEC 61223-3-5 were performed.
- FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed for each new detector of PAPAYA 3D Plus.
  The existing detector test results are as follows.
  The tests include the MTF, DQE and the dynamic range of the panoramic sensor and the cephalometric sensor. Both the MTF of the two detectors shows the resolution more than 80% at 2lp / mm and the DQE of them shows the performance of about 80% at 0lp / mm. The dynamic range of them shows more than 72dB.
  And, the additional detector test results are as follows.
  The tests include the MTF, DQE and the dynamic range of the panoramic sensor, the cephalometric sensor and the CT sensor. The MTF of the new detectors shows the resolution more than 60% at 1lp / mm and the DQE of them shows the performance of about 70% at 0lp / mm. The dynamic range of them shows more than 72dB.
  Based on the Non-Clinical Test results, even though the pixel size and active area of the new SSXI detectors are different, the diagnostic image quality of new sensors is similar to that of the predicate device and there is no significant difference in efficiency and safety.
  Please refer to Attachment X. Solid State X-ray imaging Device.
  And 3D performance tests with phantoms were performed. Test items are contrast scale, noise, slice thickness, and resolutions. All test results were within standard value range.
- PAPAYA 3D Plus meets the EPRC standards (21 CFR 1020.30. 31. 33)
- PAPAYA 3D Plus also meets the provisions of NEMA PS 3.1-3.18. Digital Imaging and Communications in Medicine (DICOM) Set.
- PAPAYA 3D Plus uses OTS software, Triana as an image viewer. Software validation report was conducted as recommended by FDA's Guidance document "Guidance for off-the-shelf Software Use in Medical Devices" The OTS Software, Triana in PAPAYA 3D Plus represents a Minor Level of Concern since failures or latent design flaws would not be expected to result in any injury to the patient or operator.
- PAPAYA 3D Plus was tested for safety and effectiveness related in Clinical Evaluation report.

All test results were satisfactory. The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

9. Conclusion

In reference to the comparison information provided in substantial equivalence chart, most of functions and electronic features are similar with predicate devices. We believe that the PAPAYA 3D Plus is safe and effective as predicate devices, and has no new indication for use. Thus PAPAYA 3D Plus is substantially equivalent to predicate devices.